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Japan

Sanitary / Phytosanitary / Food Safety

Japan Approves Two Flavorings and Revises Use Standards of Two Additives

2004

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Report Highlights:
Japan proposed to designate two flavorings, 2-ethyl-3,(5,6)-dimethylpyrazine and 2,3,5,6-tetramethylpyrazine, and revise the use standards for zinc gluconate and copper gluconate to permit their use in foods with health claims. Japan invited foreign Embassies to comment on these revisions with a deadline for comments on April 27, 2004. This proposal will be submitted to the WTO for a further opportunity for comments.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

On March 14, 2004, the Ministry of Labor, Health and Welfare (MHLW) invited foreign Embassies in Tokyo to comment on designation of two flavorings, 2-ethyl-3,(5,6)-dimethylpyrazine and 2,3,5,6-tetramethylpyrazine, and revise the use standards for zinc gluconate and copper gluconate to permit their use in foods with health claims. Foreign governments have until April 27, 2004 to comment.

MHLW will open the proposal for comments from a wider audience and notify the WTO SPS Committee before final review and adoption.

All interested parties are encouraged to send their comments well before the deadline for consideration by Foreign Agricultural Service, USDA. The office responsible for the comments is as follows:

Food Safety and Technical Services
International Trade Policy division
USDA Foreign Agricultural Service
Fax: 202-690-0677
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1. Designation of 2-ethyl-3, (5,6)-dimethylpyrazine and 2,3,5,6-tetramethylpyrazine.

The two flavorings are widely used in countries including Europe and the U.S. They have "roasted" flavor and are used in various foods, such as baked confectionary, ice cream, candy and processed meat products.

The proposed standards and specifications of the flavorings are as follows:

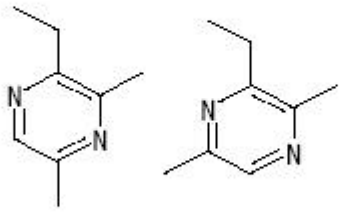
Attachment 1

2-Ethyl-3, (5or6)-dimethylpyrazine

Standard for use

It must not be used for purposes other than flavoring.

Compositional specifications



$C_8H_{12}N_2$ Mol. Wt.136.20

Mixture of 2-Ethyl-3,5-dimethylpyrazine and 2-Ethyl-3,6-dimethylpyrazine [55031-15-7]

Content Mixture of 2-Ethyl-3,5-dimethylpyrazine and 2-Ethyl-3,6-dimethylpyrazine contains not less than 95% of the total of 2-ethyl-3,5-dimethylpyrazine and 2-ethyl-3,6-dimethylpyrazine ($C_8H_{12}N_2$).

Description Mixture of 2-Ethyl-3,5-dimethylpyrazine and 2-Ethyl-3,6-dimethylpyrazine occurs as a colorless to slightly yellow, clear liquid. It has a characteristic odor

Identification Determine the infrared absorption spectrum of Mixture of 2-Ethyl-3,5-dimethylpyrazine and 2-Ethyl-3,6-dimethylpyrazine as directed under the Liquid Film Method in Infrared Spectrophotometry, and compare the spectrum with the Reference Standard. Both spectra exhibit a similar intensity of absorption at the same wave number.

Purity (1) Refractive index n_D^{20}: 1.496–1.506

(2) Specific gravity 0.950–0.980

Assay Proceed as directed under Method 1 of Gas Chromatography in the Flavor Substance Tests, using operating conditions (1).

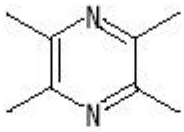
Attachment 2

2,3,5,6-Tetramethylpyrazine

Standard for use

It must not be used for purposes other than flavoring.

Compositional specifications



$C_8H_{12}N_2$ Mol. Wt. 136.20

Tetramethyl-1,4-diazine [1124-11-4]

Content 2,3,5,6-Tetramethylpyrazine contains not less than 95% of 2,3,5,6-tetramethylpyrazine ($C_8H_{12}N_2$).

Description 2,3,5,6-Tetramethylpyrazine occurs as white crystals or powder, and has a characteristic odor.

Identification Determine the infrared absorption spectrum of 2,3,5,6-Tetramethylpyrazine as directed under the Paste Method in Infrared Spectrophotometry, and compare the spectrum with the Reference Standard. Both spectra exhibit a similar intensity of absorption at the same wave number.

Purity Melting point 85–90℃

Assay Weigh exactly 0.20 g of 2,3,5,6-Tetramethylpyrazine, and dissolve it in ethanol to make exactly 20 ml. Proceed as directed under Method 1 of Gas Chromatography in the Flavor Substance Tests, using operating conditions (1).

2. Revision of the use standards for zinc gluconate and copper gluconate

Attachment 4.

The use standards for Zinc Gluconate and Copper Gluconate will be revised so that these substances can be used in foods with health claims.*

1. Zinc Gluconate

Current standard	6.0 mg/L (as Zinc) in each human milk substitute.
Added standard	The recommended daily portion of each food with health claim must not contain more than 15 mg as Zinc.

2. Copper Gluconate

Current standard	6.0 mg/L (as Copper) in each human milk substitute.
Added standard	The recommended daily portion of each food with health claim must not contain more than 5 mg as Copper.

Note:
Foods with health claims refer to all foods that comply with the specifications and standards established by the national government, considering necessary requirements such as safety and efficacy, based on the Enforcement Regulations under the Food Sanitation Law.